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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
GOLLAMUDI, SHARMILA S	
ART UNIT	**PAPER NUMBER**
1616	

DATE MAILED: 04/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/767,686	PIAO ET AL.	
	Examiner	Art Unit	
	Sharmila S. Gollamudi	1616	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on 9/2/06.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-23 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 1-23 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Receipt of Amendments/Remarks and the Information Disclosure Statement filed on 9/2/05 and the Information Disclosure Statement filed 8/4/05 is acknowledged. Claims **1-23** are pending in this application.

Claim Rejections – 35 USC § 103

The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,702,717) in view of EP 0092918 is withdrawn in view of the amendments of 9/2/05.

The rejection of claims 1-23 under 35 U.S.C. 103(a) as being unpatentable over Cha et al (5,702,717) in view of Shah et al (6,451,346) is withdrawn in view of the amendments of 9/2/05.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321I may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

The rejection of claims 1-17 under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 09/827100 (which has been allowed) in view Shah et al (6,451,346) is withdrawn in view of the

amendments filed 9/2/05. Note that the instant application is not a divisional of 09/827100 as argued by applicant.

Claims 1-8 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/186462.

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

Copending application independent claim 1, independent claim 8, and independent claim 28 are directed to a composition comprising one or more biodegradable copolymeric drug carriers comprising 1) AB or ABA or BAB block copolymers wherein A block is a polyester and

B clock is a PEG and 2) a liquid PEG, PEG derivative or a mixture thereof. Dependent claims 7, 14, and 34 further comprises a drug. Lastly, copending claims 35-41 are directed to a method of preparing the biodegradable polymeric system of claim 1, 8, and 28 respectively.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter since the instant claims are directed to a combination of two triblock copolymers and a drug copending claims may contain one or more biodegradable triblock copolymers and a drug. Thus, the two applications are obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant's main argument is that instant invention is directed to a polymeric system that has reverse thermal gelation properties and '462 does not claim a polymer mixture with reverse thermal gelation properties. Applicant argues that '462 comprises a high weight percentage of the hydrophobic blocks and not instantly claimed amount. Applicant argues that the '462 is directed to a water-soluble low molecular weight PEG and mixtures thereof.

Applicant's arguments filed 9/2/05 have been fully considered but they are not persuasive. Firstly, the examiner points out that '462 claims the same biodegradable polyester polymer and biodegradable polyethylene glycol polymer with the same molecular weight and thus '462 must also have the same properties as the instant invention, i.e. reverse gelation properties. Note page 11-12 of the specification of '462 which further substantiate the examiner's position and clearly states the polymeric system has reverse gelation properties. Thus

although '462 does not claim this inherent property, i.e. reverse gelation properties, the biodegradable polymers claimed '462 have this property. Secondly, with regard to the weight percent of the hydrophobic block polymer, the examiner points out that '462 claims 20-99% which encompasses the claimed range of 51-83%. Therefore, it is the examiner's position that the claims are obvious over each other.

Claims 1-8 and 18-19 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending Application No. 10/167768.

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

Copending application independent claim 1, independent claim 8, independent claim 15, and independent claim 22, are directed to a composition comprising one or more biodegradable copolymeric drug carriers comprising 1) AB or ABA or BAB block copolymers wherein A block is a polyester and B clock is a PEG and 2) a liquid PEG, PEG derivative or a mixture thereof. Dependent claims 6, 13, and 20 further comprises a drug. Lastly, copending claims 29-36 are directed to a method of preparing the biodegradable polymeric system.

Although the conflicting claims are not identical, they are not patentably distinct from each other because they are directed to similar subject matter since the instant claims are directed to a combination of two triblock copolymers and a drug and copending claims may contain one or more biodegradable triblock copolymers and a drug. Thus, the two applications are obvious modifications of each other.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant argues that the arguments pertaining to '462 are applicable here.

Applicant's arguments filed 9/2/05 have been fully considered but they are not persuasive.

The examiner incorporates the above response to provisional application '462 herein and maintains the rejection.

Claims 1-17 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of copending

Application No. 10/734740 in view of Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of

between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19 are directed to a process of preparing the polymeric system of claim 1.

Copending application independent claim 1, independent claim 4, independent claim 8, and independent claim 12, are directed to a composition comprising a biodegradable ABA or BAB block copolymers wherein A block is a polyester and B clock is a PEG and an effective amount of drug. Claim 18 and 23 are directed to a method of administering the polymeric drug delivery system wherein the system is liquid and administering the composition to a warm-blooded animal.

The copending claims do not claim the mixture of two triblock copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine utilize a mixture of two tri-block copolymers with different properties. One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Therefore, claiming a mixture of tri-block copolymers is an obvious modification since the prior art teaches the manipulation of tri-block copolymer to control the release rate of the drug.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Response to Arguments

Applicant argues that '740 is not directed to a polymeric system with reverse gelation temperatures. Applicant argues that Shah teaches polymers that are pH sensitive and lose their gelation properties art a pH of above 5.

Applicant's arguments filed 9/2/05 have been fully considered but they are not persuasive. The examiner points out that the polymers claimed in '740 have the capability of gelling at a certain temperature. The examiner points out that page 6, lines 5-10 of '740 states that the polymeric system does not gel at temperatures of up to 50 degrees Celsius. Clearly the polymers are capable of gelling at temperatures above 50 degrees Celsius and thus have reverse gelation properties. Secondly, the examiner points out that '740 is claming a substantially similar triblock copolymer with the overlapping weight percent of the polyester hydrophobic and PEG hydrophilic polymers and thus '740's polymers must have the same properties. The examiner further points out that applicant has not shown that the polymers do not have reverse gelation properties and has merely argued this. The examiner points out that applicant's arguments cannot

take the place of evidence and applicant has not submitted any evidence to demonstrate that '762 biodegradable polymers do not reverse gelation properties.

With regard to Shah, the examiner's merely relies on Shah to teach the motivation to combine two triblock copolymers. Thus, applicant's arguments regarding Shah's specific polymers are irrelevant since this is not the premise of the rejection. Moreover, the examiner points out that Shah clearly discloses polymers that have reverse gelation properties and it is irrelevant that they do not have this property at a specific pH since the only requirement in the instant claims are that the polymers have reverse gelation properties. The instant claims do not require the polymers to maintain reverse gelation properties at a certain pH and thus this argument is moot.

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,592,899 in view Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said

Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19are directed to a process of preparing the polymeric system of claim 1.

US '899 claim 22 is directed to a biodegradable aqueous drug solution and method of administering the drug solution comprising (a) an effective amount of a drug; (b) a biodegradable polyester oligomer and (c) a biodegradable AB-type, ABA-type, or BAB-type block copolymer capable of solubilizing said drug in a hydrophilic environment, comprising: I) 50.1 to 65% by

weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and ii) 35 to 49.9% by weight of a hydrophilic B polymer block comprising a polyethylene glycol (PEG), and wherein the tri-block copolymer has a weight-averaged molecular weight of between 2400 to 4999; and (d) an aqueous solution.

US patent does not claim the mixture of two tri-block copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine utilize a mixture of two tri-block copolymers with different properties. One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Therefore, claiming a mixture of tri-block copolymers is an obvious modification since the prior art teaches the manipulation of tri-block copolymer to control the release rate of the drug.

Response to Arguments

Applicant main argument is that instant invention is directed to a polymeric system that has reverse thermal gelation properties and '899 does not claim a polymer mixture with reverse thermal gelation properties.

Applicant's arguments filed 9/2/05 have been fully considered but they are not persuasive. The examiner points out that the polymers claimed in '899 would have the capability of gelling at a certain temperatures since '899 is claming a substantially similar triblock copolymer with the overlapping weight percent of the polyester hydrophobic and PEG hydrophilic polymers; thus '899's polymers must have the same properties. The examiner further points out that applicant has not shown that the polymers do not have reverse gelation properties and has merely argued this. The examiner points out that applicant's arguments cannot take the place of evidence and applicant has not submitted any evidence to demonstrate that '899 biodegradable polymers do not reverse gelation properties.

With regard to Shah, the examiner's merely relies on Shah to teach the motivation to combine two triblock copolymers. Thus, applicant's arguments regarding Shah's specific polymers are irrelevant since this is not the premise of the rejection. Moreover, the examiner points out that Shah clearly discloses polymers that have reverse gelation properties and it is irrelevant that they do not have this property at a specific pH since the only requirement in the instant claims are that the polymers have reverse gelation properties. The instant claims do not require the polymers to maintain reverse gelation properties at a certain pH and thus this argument is moot.

Claims 1-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims of U.S. Patent No. 6,201,072; 6,117,949; 6,004,573 in view Shah et al (6,451,346). Although the conflicting claims are not identical, they are not patentably distinct from each other because:

Instant application's claim 1 is directed to an aqueous biodegradable polymeric drug delivery system comprising (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons.

Instant independent claim 9 is directed to a method of administering the aqueous biodegradable drug delivery system wherein the system contains (a) an effective amount of a drug and (b) a biodegradable polymeric system possessing reverse thermal gelation properties comprising a mixture of at least a Component I triblock copolymer and a Component 11 triblock copolymer, said triblock copolymers comprising biodegradable polyester A-polymer blocks and polyethylene glycol B-polymer blocks, wherein the B-polymer block of said Component I triblock copolymer has an average molecular weight of 900 to 2000 Daltons and the B-polymer

block of said Component 11 triblock copolymer has an average molecular weight of 600 to 2000 Daltons, and wherein said Component I triblock copolymer has an average molecular weight of between 2500 to 8000 Daltons and said Component 11 triblock copolymer has an average molecular weight of between 800-7200 Daltons, maintaining the system as a liquid, administering the composition as a liquid and wherein the system forms a gel at body temperature.

Instant claims 18-19are directed to a process of preparing the polymeric system of claim 1.

US '573 is directed to a an aqueous biodegradable polymeric drug delivery composition possessing reverse thermal gelation properties comprised of an aqueous phase having uniformly contained therein: (a) an effective amount of a drug; and (b) a biodegradable ABA-type block copolymer of the formula: PLGA-PEG-PLGA where PLGA is a hydrophobic poly(lactide-co-glycolide) copolymer that comprises the A-blocks and PEG is a hydrophilic polyethylene glycol polymer that comprises the B-block, said block copolymer having an average molecular weight of between about 3100 and 4500 wherein, in the block copolymer, the PLGA A-blocks comprise about 51 to 83% by weight of said copolymer and the PEG B-block comprises about 17 to 49% by weight of said copolymer. Further, US Patent claim 12 is directed to a method of administering the above system, by providing for said system, maintaining said system as a liquid below gelation temperature, and administering the composition to an animal; wherein the system forms a gel at body temperature.

US'072 is directed an aqueous biodegradable polymeric drug delivery composition

possessing reverse thermal gelation properties comprised of an aqueous phase having uniformly contained therein: (a) an effective amount of a drug and (b) a biodegradable ABA- or BAB-type tri-block polymer, said ABA triblock comprises: i) about 51 to 83% by weight of a biodegradable, hydrophobic A polymer block comprising a biodegradable polyester, and ii) about 17 to 49% by weight of a biodegradable, hydrophilic B polymer block comprising a polyethylene glycol(PEG), and wherein the tri-block copolymer having an average molecular weight of between about 2000 to 4990 and possessing reverse thermal gelation properties. Further, US Patent claim 26 is directed to a method of administering the above system, by providing for said system, maintaining said system as a liquid below gelation temperature, and administering the composition to an animal; wherein the system forms a gel at body temperature.

US'949 is directed to an aqueous biodegradable polymeric drug delivery composition possessing reverse thermal gelation properties comprised of an aqueous phase having uniformly contained therein: (a) an effective amount of a drug; and (b) a biodegradable ABA- or BAB-type triblock polymer said ABA triblock having the formula: PL(G).sub.z-1 A-PEG-PL(G).sub.z-1 A and said BAB triblock having the formula: PEG-PL(G).sub.z-1 A-PEG wherein z is an integer of 1 or 2, wherein the A block is represented by PL(G).sub.z-1 A such that when z is 2 the A block is a poly(lactide-co-glycolide) or PGLA copolymer, and when z is 1 the A block is a poly(lactide) or PLA polymer and wherein the B block is represented by PEG which is a hydrophilic polyethylene glycol polymer, said triblock polymer having a weight average molecular weight of between about 2000 to 4990, and wherein, in the triblock polymer, the PL(G).sub.z-1 A A-block comprises about 51 to 83% by weight of said polymer and the PEG B-block comprises about 17 to 49% by weight of said polymer. Further, US Patent claim 24 is

directed to a method of administering the above system, by providing for said system, maintaining said system as a liquid below gelation temperature, and administering the composition to an animal; wherein the system forms a gel at body temperature.

The above US patent do not claim the mixture of two tri-block copolymers.

Shah et al teach a biodegradable thermosensitive hydrogel for sustained release of biologically active agents that gels at body temperature. The system contains AB di-block or ABA tri-block copolymers. The biodegradable copolymers are made of hydrophobic A block segments such as polyesters and hydrophilic B block such as PEG. Shah teaches the release rate of the system, i.e. continuous or discontinuous, linear or non-linear, etc, can be accomplished by using one or more polymer compositions drug loading, excipients, and other modifications. See column 11, lines 1-10. The examples demonstrate the change of release and degradation by using one tri-block copolymer solution versus two tri-block copolymer solutions.

It would have been obvious to one of ordinary skill in the art at the time the invention was made to combine utilize a mixture of two tri-block copolymers with different properties. One would have been motivated to do so since Shah teaches different copolymer blends allows for the variation of the release rate of the delivery system. Therefore, claiming a mixture of tri-block copolymers is an obvious modification since the prior art teaches the manipulation of tri-block copolymer to control the release rate of the drug.

Response to Arguments

Applicant argues that the US patent do not teaches mixture of triblock copolymers wherein one copolymer has a lower gelation temperature than the other. Applicant argues that

Shah teaches polymers that are pH sensitive and lose their gelation properties art a pH of above 5.

Applicant's arguments filed 9/2/05 have been fully considered but they are not persuasive. The examiner points out that the examiner relies on Shah to teach the state of the art wherein it is known to combine different triblock copolymers with different properties to manipulate the release rate of the polymeric delivery system. The examiner points out that Shah is relied upon for this specific teaching and not for the specific polymers since the US patents claim the same polymers as the instant application and the only teaching lacking is the mixture of the triblock copolymers. The examiner points out that is two different triblock copolymers are used then the properties such as the gelation temperature of the triblock polymers would obviously be different.

Conclusion

The instant claims are free from prior art. The closest prior art US 5,702,717 does not disclose or suggest 1) a mixture of triblock copolymers or 2) the instant concentration of the hydrophobic polymer and hydrophilic polymer. US '717 teaches the hydrophilic polymer is contained in an amount of 50-85% and the hydrophilic polymer must be in an amount of at least 50% and preferably higher to remain water-soluble. Further, US '717 teaches the hydrophobic polymer is in an amount of 15-50%. Thus, the instantly claimed range would not be obvious over US '717.

US 6,004,573 is made of record which teaches the instant triblock polymer and concentration; however US '573 does not discloses a mixture of different triblock copolymers.

US '573 is unavailable as prior art under 103 (c) since applicant has made the appropriate statement in parent application 09/559799.

However, all the claims are rejected under obviousness double patenting.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharmila S. Gollamudi whose telephone number is 571-272-0614. The examiner can normally be reached on M-F (8:00-5:30), alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz can be reached on 571-272-0887. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Sharmila S. Gollamudi
Examiner
Art Unit 1616

SREENI PADMANABHAN
SUPERVISORY PATENT EXAMINER